

Appln No. 09/772,634

Amdt date April 29, 2004

Reply to Office action of November 4, 2003

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Currently Amended) A process for enhancing the solubility of a blood protein solution comprising:

(a) adding to a blood protein solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein; and

(b) lyophilizing the solution of step (a) to form a lyophilized complex of the protein and hydroxypropyl- $\alpha$ -cyclodextrin without further heating of the formed complex.

2. (Previously Presented) The process according to claim 1, further comprising reconstituting the lyophilized complex.

3. (Currently Amended) The process according to claim 1, further comprising heating the blood protein solution, before ~~or~~ ~~after~~ adding hydroxypropyl- $\alpha$ -cyclodextrin, at a temperature of at least 60°C for a time sufficient to inactivate any viruses present in the complex.

4. (Previously Presented) The process according to claim 3 wherein the blood protein solution is heated for at least 10 hours.

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5. (Previously Presented) The process according to claim 3 wherein the blood protein solution is heated to a temperature of at least 80°C for at least 72 hours.

6. (Currently Amended) The process according to claim 3 wherein the blood protein solution is heated to a temperature of at least 100°C for at least 1 hour.

7. (Original) The process according to claim 1, further comprising subjecting the blood protein solution, before or after adding the hydroxypropyl- $\alpha$ -cyclodextrin, to a solvent detergent viral inactivation step.

8. (Original) The process according to claim 1, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

9. (Original) The process according to claim 1, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

10. (Previously Presented) The process according to claim 2, wherein the protein is present in the reconstituted complex in an amount greater than about 0.1% wt/vol.

11. (Currently Amended) The process according to claim 2 wherein the protein is present in the reconstituted complex in an amount from about 1% wt/vol to about 8 % wt/vol.

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12. (Original) The process according to claim 1 wherein the protein is selected from the group consisting of albumin, Factor II, Factor VII, Factor VIII, Factor IX, Factors X and X<sub>a</sub>, fibrinogen, antithrombin III, transferrin, haptoglobin, gamma globulins, fibronectin, protein C, protein S, thrombin and C1-inhibitor.

13. (Original) The process according to claim 1, wherein the protein is fibrinogen.

14. (Original) The process according to claim 12, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

15. (Original) The process according to claim 12, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 2% wt/vol. to about 12% wt/vol.

16. (Previously Presented) The process according to claim 12, wherein the fibrinogen is present in the reconstituted complex in an amount greater than about 1% wt/vol.

17. (Previously Presented) The process according to claim 12, wherein the protein is fibrinogen, and the fibrinogen is present in the reconstituted complex in an amount from about 3% wt/vol. to about 10% wt/vol.

18. (Currently Amended) A process for enhancing the stability of a fibrinogen solution comprising:

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(a) adding to a fibrinogen solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein;

(b) lyophilizing the solution of step (a) to form a lyophilized complex of fibrinogen and hydroxypropyl- $\alpha$ -cyclodextrin; and

(c) reconstituting the lyophilized complex without further heating of the formed complex.

19. (Currently Amended) A lyophilized complex of a blood protein and hydroxypropyl- $\alpha$ -cyclodextrin prepared by:

(a) adding to a blood protein solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein; and

(b) lyophilizing the solution of step (a) to form the lyophilized complex without further heating of the formed complex.

20. (Currently Amended) A blood protein product prepared by:

(a) adding to a blood protein solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein;

(b) lyophilizing the solution of step (a) to form a lyophilized complex of the protein and hydroxypropyl- $\alpha$ -cyclodextrin; and

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(c) reconstituting the lyophilized complex without further heating of the formed complex.

21. (Currently Amended) A fibrinogen product prepared by:

(a) adding to a fibrinogen solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein;

(b) lyophilizing the solution of step (a) to form a lyophilized complex of fibrinogen and hydroxypropyl- $\alpha$ -cyclodextrin; and

(c) reconstituting the lyophilized complex without further heating of the formed complex.

22. (Original) A blood protein product comprising a lyophilized solution of a stable complex of protein and hydroxypropyl- $\alpha$ -cyclodextrin.

23. (Previously Presented) The product according to claim 22, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

24. (Previously Presented) The product according to claim 22, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

25. (Original) The product according to claim 22, wherein the blood protein is fibrinogen.

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26. (Original) A stabilized blood protein solution comprising a complex of the blood protein and hydroxypropyl- $\alpha$ -cyclodextrin.

27. (Original) The solution according to claim 26, wherein the protein is present in the complex in an amount greater than about 3% wt/vol.

28. (Previously Presented) The product according to claim 26, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the complex in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

29. (Previously Presented) The process according to claim 26, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the complex in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

30. (Original) The product according to claim 26, wherein the blood protein is fibrinogen.